

Remarks

The pending Office Action has been carefully considered. Eighteen claims are pending in this application, numbered 1, 3, 5-18, 21 and 22. Claim 1 is the sole independent claim. Claims 1 has been amended. Claim 23 is newly added.

The present invention as claimed in newly amended independent claim 1 is a two-component ostomy device that is capable of being coupled together by an adhesive. Many coupling systems are capable of being coupled together by mechanical interlockings, one of which is present on the body attaching wafer component and another of which is present on the pouch component. The present invention is directed to an adhesively coupleable, two-component ostomy device.

The present invention is a two- component ostomy device that is adhesively coupleable to and separable from each other along a pressure sensitive adhesive interface that is between the two components. Each of the two components, the body attaching wafer component and the pouch component, has a surface on the opposite side of the adhesive interface. One of these two components has a closed cell foam surface. The adhesive interface is coated onto at least one of the two surfaces.

Along the adhesive interface, the two components adhesively couple and separate. The adhesive interface includes one or more polysiloxanes or one or more polysiloxanes and at least one silicate resin including their blends and reaction products. The adhesive interface is resealable and resistant to migration of stomal fluids into it.

The Examiner rejected the formerly pending claims under 35 U.S.C. 103 in view of Doyle, et al. (“Doyle”), Steer, et al. (“Steer”) and Hahn, et al. (“Hahn”). Doyle was applied singly or in combination with Steer and Hahn.

Both Doyle and Steer are commonly assigned with the present application.

The present invention, as claimed in newly amended claim 1, is neither anticipated nor obvious in view of the cited references, applied singly or in combination.

The present invention as newly claimed is directed to a two-component adhesively coupleable and separable ostomy device. This coupling and separation occurs along an adhesive interface wherein each component has a surface and one of those surfaces is a closed cell foam. Support for this structure can be found, for

example, in paragraph [0044] of the published application.

This adhesive interface includes polysiloxanes and their combinations as claimed in amended claim 1.

The references cited by the Examiner disclose and teach structures that are very different than the one presently claimed. The present invention is a creative and unexpected solution to a major problem of two-piece ostomy devices that are capable of adhesively coupling and separating.

In particular, Doyle is directed to a pressure sensitive adhesive for joining a medical device to the skin. It is not concerned with adhesively coupling and separating the two components of an ostomy device. It is not concerned with resealing of the adhesive interface between two components. It is not concerned with a closed cell foam surface on one of the two components with a polysiloxane adhesive coated onto one of the component surfaces.

Doyle is concerned with attachment of the devices directly to the skin. The Doyle text cited by the Examiner at column 6, lines 13-19, refers to a polymer surface on a skin barrier as taught by Steer. This refers to the attachment by adhering of a mechanical coupling to a pad or pouch. There is no teaching or suggestion of an adhesive by Doyle other than one between the device and the wearer's skin. There is no teaching in Steer of an adhesive joining the pad and \_\_\_\_\_ or wafer.

Steer is concerned with a two-piece ostomy device, however, the two components are joined by two interlocking mechanical couplings, one on the body attaching wafer and one on the pouch. There is no adhesive coupling, no adhesive interface, no closed cell foam, no separation along the interface, no polysiloxane type adhesive.

Doyle is concerned with and directed solely to the adhesion of a medical device to the skin.

Hahn discusses polysiloxane adhesives, however, it is not taught or suggested to be used in an ostomy device as presently claimed.

These references are unconcerned with the creative and surprisingly effective adhesive structure between the two components of the claimed ostomy device. The use of a closed cell foam surface on one component of a two-component ostomy device

with a polysiloxane adhesive interface along which to couple and separate the two components is not mentioned, considered, suggested, taught or referred to in the cited references. Heretofore, there was no such thing as a coupleable and separable, two-component ostomy device having a polysiloxane adhesive as an adhesive interface, as presently claimed.

Accordingly, allowance of this application is respectfully solicited.

Respectfully submitted,

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